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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/243,016	02/02/1999	DIRK LENZ	BEIERSDORF54	1839

7590 08/23/2004

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/243,016

Applicant(s)

LENZ ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time, and amendment under 1.111, both filed 06/29/2004.

The pending claims are 1, 3, and 5-13.

1. The set-forth guidelines for the specification layout have not been followed. Thus, the guidelines are re-suggested for applicant's use.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a).

"Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 103

2. Claims 1, 3, 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 89/04649 ('649), by itself or in combination with US 3,908,645 ('645).

WO '649 discloses an occlusive opaque eye patch comprising:

- 1) an outer polymeric foam layer,
- 2) intermediate foam layer,
- 3) inner pressure sensitive adhesive layer, and
- 4) inner member of black felt which is dimensioned so that it can be placed concentrically within the edges of the adhesive layer so that peripheral portion of the adhesive is exposed to be attached to the skin. The adhesive portion is secured with a cover that can be peeled off at use. See page 1, lines 3-6; page 5, lines 1-12, 23-30; page 6, lines 1-3; page 9, lines 12-17.

WO '649 does not disclose the foam material as polyurethane or the method of making the foam.

US '645 discloses an eye bandage comprising a layer of polyurethane foam, covered with non-woven web material of polyester on one side and pressure sensitive adhesive layer on the other side. The pressure sensitive adhesive is covered with a release liner. The reference disclosed foaming the polyurethane between two liners and the foam is then split or slit through its center producing two identical thinner sheets of foam having minimum reflectance (opaque). See abstract; col.1, lines 44-58; col.2, lines 30-43; col.3, lines 31-44; col.4, lines 3-4, 35-50; col.6, lines 9-16.

Applicants failed to show criticality or superior and unexpected results in the sequence of arranging the layers or having the three layers made of foam. Felt is also a kind of foam, is not solid or compact.

Accordingly, it would have been obvious for one having ordinary skill in the art at the time of the invention to produce an occlusive patch consisting of three layers of foam material, and use the polyurethane of US '645, motivated by the teaching of US '645 that the two layers of foam provide very low reflectance, with reasonable expectation of success of the delivered patch as an ophthalmic light occlusive patch.

Applicant's Arguments

Applicant's arguments filed 06/29/2004 have been fully considered but they are not persuasive. The main gist of applicants' argument against the 103 rejection is that Sandvig teaches the use of polyurethane any of polyurethane, polyether, polyolefin,

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etc., which group of polymer genera represent perhaps hundred of thousands of different foam species. Yet, Examiner has not provided any technical reasoning to explain why combining Morgan and Sandvig would lead persons in the art to arrive at the limitation in claim 1.

The data in examples 1-3 demonstrate that the claimed article is superior over alternatives known in the art, and thus, are sufficient to rebut a prima facie case of obviousness. MPEP 716.02(a). From these data, it is clear that the plaster prepared from aliphatic polyurethanes provided far better air and water permeability properties than those made with aromatic polyurethanes. Most importantly, Morgan and Sandvig do not teach or suggest the desirability of aliphatic polyurethanes. Further, there is nothing in either reference that would have made the unexpected and superior permeability properties reasonably expected.

It is well established that a proper reference under 35 USC 102 or 103 must be enabling in the sense of 35 USC 112, paragraph 1. It is suggested that the Morgan and Sandvig references are not enabling to that extent. The proper test of a description in a publication as a bar to a patent as the clause is used in section 102(b) requires a determination of whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought. In view of the results described above, it is clear that neither Morgan nor Sandvig, taken individually or in combination, would provide

sufficient guidance to provide a plaster with the objectively measured permeability properties. Nor has Examiner provided such a rationale.

Examiner's Position

In response to applicant's argument above, it is the examiner position that the rejection made is an obviousness rejection, and it is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). The art recognized the use of polyurethane in general in the patches used to cover the eye. EP '469 disclosed two foam layers. US '645 also disclosed two layers of polyurethane foam.

The results provided by applicant's examples and tables 1 do not compare the prior art patch having the same dimensions to those of the present invention, instead comparing different embodiments of the present invention that have different dimensions. The patch of examples 1 and 2 have more than one ply, while that of example 3 has only one ply, therefore, it is expected to have different permeability properties based on the different thickness. In any events, it is noted that the features upon which applicant relies (i.e., permeability properties) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The conclusion of obviousness under U.S.C. 103(a) does not require absolute predictability, only a reasonable expectation of success, and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Morgan and Sandvig are related to the ophthalmic patches. The art recognized the use of foamed layers in the eye patch and the effectiveness of having more than one foamed layers in the eye patch regarding its resiliency and light reflection, as well as absorbency and this would have motivate one having ordinary skill in the art to select any other layers in the eye patch to be foamed to add more comfortability to the patient. Thus, one having ordinary skill in the art at the time of the invention would have been motivated to produce an occlusive

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patch consisting of three layers of foam material, and use the polyurethane of US '645, motivated by the teaching of US '645 that the two layers of foam provide very low reflectance, with reasonable expectation of success of the delivered patch as an ophthalmic light occlusive patch.

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595.

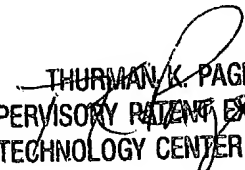
The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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